

In re Application of:  
Hall et.al.  
Application No.: 09/218,913  
Filed: December 22, 1998  
Page 6

PATENT  
Attorney Docket No.: AERO1120

**REMARKS**

These remarks are in response to the Office Action mailed July 1, 2005.

Claims 1 and 19 have been amended. Claims 11-13 have been previously withdrawn. Claim 30 has been added. Amendment to claims 1 and 19 and new claim 30 are supported in the specification and do not add new matter nor raise new issues.

Applicants and Applicants' representatives gratefully acknowledge the careful consideration of the application and helpful suggestions made by the Examiner in the telephone interview held on September 14, 2005.

Accordingly, upon entry of the amendment, claims 1-10, 14 and 16-30 are pending and at issue.

**I. Amendments to the claims**

Claims 1 and 19 have been amended to claim the subject matter of the invention with greater particularity and specificity. Claim 1 has been amended to recite:

A method for accelerating the rate of mucociliary clearance in a subject with chronic obstructive lung disease (COLD) comprising administering to the subject a therapeutically effective mucociliary clearance stimulatory amount of a composition comprising a substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain.

Claim 19 has been amended to recite:

A method for accelerating the rate of mucociliary clearance in a subject having a chronic obstructive lung disease (COLD) comprising administering to the subject a therapeutically effective mucociliary clearance stimulatory amount of a composition comprising a substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain and a physiologically acceptable carrier, wherein the inhibitor is selected from a group consisting of: SEQ ID NO.: 49; SEQ ID NO.: 2; SEQ ID NO.: 45; SEQ ID NO.: 47; SEQ ID NO.: 71; SEQ ID NO.: 70; SEQ ID NO.: 4; SEQ ID NO.: 5; SEQ ID NO.: 6; SEQ ID NO.: 7; SEQ ID NO.: 3; SEQ ID NO.: 50; SEQ ID NO.: 1; SEQ ID NO.: 52; and SEQ ID NO.: 8.

The phrase, "chronic obstructive lung disease" is supported in the specification:

Mucociliary dysfunction, characterized by the inability of ciliated epithelium to clear mucus and sputum in lung airways, is a serious complication of *chronic obstructive lung diseases* such as Chronic Bronchitis (CB), Bronchiectasis (BE), asthma and, especially, Cystic Fibrosis (CF) [emphasis added; page 1, lines 14-17];

A preferred application for placental bikunin, isolated domains, and other variants is for stimulating mucociliary clearance in CF patients as part of disease therapy and management. These methods and compositions reduce or eliminate mucus and sputum buildup in lung airways in patients with *chronic obstructive lung disease*, thereby reducing the risk of secondary lung infections and other adverse side effects, as well as avoiding or delaying the need for lung transplant surgery in CF patients [emphasis added; page 8, lines 20-26]; and

For stimulating the rates of mucociliary clearance in patients with *chronic obstructive lung disease*, the proteins of the instant invention may be used like *aprotinin Trasylol* while taking into account the differences in potency [emphasis added; page 9, lines 29-31];

Thus, based on the foregoing, the claimed methods to accelerate the rate of mucociliary clearance in a subject with chronic obstructive lung disease. Therefore, no new matter has been added, and the amendments are fully supported in the application as filed.

## **II. Rejection Under 35 U.S.C. §102(e)**

Claims 1-10, 14 and 16-29 are rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Patent No. 6,583,108 to Tamburini et al. (hereinafter, "Tamburini"). Applicants respectfully traverse this rejection.

According to the Office Action, claims 1-10, 14 and 16-29 are under consideration as they pertain to human bikunin, or SEQ ID NO:52 (see the top of page 2 of the Office Action) and its use for treatment of adult respiratory distress syndrome (ARDS) and emphysema (column 15, lines 6-11 and 14-16; and column 18, last sentence). Further, that according to the Office Action, ARDS is a general description for *any* disease related to difficulties of breathing, and that the Examiner understands the term "mucociliary clearance" to mean "clearing *liquids* from the airway of the lung (see page 2 of the Office Action)."

To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131. Further, the claimed invention must be distinct from what is apparently inherent in the reference, and the reference must be enabling to place the allegedly disclosed matter in the possession of the public. *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); and *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

Tamburini discloses human placental bikunin and fragments thereof. Tamburini further discloses that the compositions can be used to treat ARDS (see col.15, lines 13-17).

Applicants submit that ARDS is *not* the same as a chronic obstructive lung diseases (COLD; COLD is also called chronic obstructive pulmonary disease, or COPD). Exhibits A and B, describe definitions for ARDS (Exhibit A, MedicineNet.com; and Exhibit B, DrKoop.com). ARDS stands for “acute respiratory distress syndrome” or “sudden respiratory failure due to the rapid accumulation of fluid in the lungs following abrupt increase in the permeability of the normal barrier between the capillaries and the air sacs in the lungs...When the air sacs collapse or fill up with fluid, the lungs can no longer properly fill with air and the lungs become stiff...ARDS is the *most serious* response to acute lung injury.” See Exhibit A. Similarly, Exhibit B states that “ARDS is a life-threatening condition (see page 1)...ARDS is a medical emergency. It can be caused by any major lung inflammation or injury [including] pneumonia, septic shock, trauma, aspiration of vomit, or chemical inhalation (see page 2).” Other definitions of ARDS are similar to that stated above, Exhibits A and B are provided as samples of what one skilled in the art understands to be ARDS. Also, Exhibits A and B were inadvertently not attached in the response to the Office Action mailed February 25, 2005, which was filed June 2, 2005.

In contrast, chronic obstructive lung diseases (COLD; a.k.a. chronic obstructive pulmonary disease, COPD) is “any disorder that persistently obstructs bronchial air flow. COLD mainly involves two related diseases – chronic bronchitis and emphysema (see Exhibit C, MedicineNet.com). Another chronic obstructive lung disease is cystic fibrosis (CF). Both chronic bronchitis and CF are characterized by a production of sputum or thick mucus (see Exhibit D, MedicineNet.com; and Exhibit E, CysticfibrosisINFO.net).

In short, COLD and ARDS are two distinct diseases. ARDS is an “acute” lung injury, caused by rapid accumulation of fluid in the lungs. COLD is a “chronic” disease, persisting over a long period of time. Thus, accelerating the rate of mucociliary clearance in a subject with COLD, is distinct from ARDS. Therefore, the claimed invention is patentably distinct over Tamburini.

Applicants also submit that Tamburini is not enabling for the claimed invention, and that one of ordinary skill in the art would not recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation. *In re Wyer*, 655 F.2d 221, 226, 210 USPQ 790 (CCPA 1981) (*quoting, I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743 (S.D.N.Y. 1966)). *See also, In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619 (Fed. Cir. 1985).

Tamburini does not disclose methods to accelerate the rate of mucociliary clearance in a subject with chronic obstructive lung disease. The claimed invention is supported by Examples 11-16, which describe many experiments testing and determining the function of human placental bikunin for inhibiting potential difference and sodium ion exchange, and increasing tracheal mucus velocity (TMV).

Thus, based on the foregoing discussion, Applicants submit that Tamburini cannot anticipate the claimed invention, because Tamburini does not inherently or expressly teach each and every element of claimed invention.

Accordingly, withdrawal of the rejection of claims 1-10, 14 and 16-29 under 35 U.S.C. § 102(e) is respectfully requested.

### **III. Rejections Under 35 U.S.C. § 103(a)**

Claims 1-10, 14 and 16-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Delaria et al. in view of Rasche et al, Fritz et al., and O’Riordan et al. (hereinafter, “Delaria,” “Rasche,” “Fritz,” and “O’Riordan,” respectively). Applicants respectfully traverse this rejection.

According to the Office Action, the prior art allegedly provides the teaching to obtain the human placental bikunin of SEQ ID NO: 52, the motivation and expectation of success to use the human bikunin in the treatment of human disease such as ARDS, and, therefore, *prima facie*, obviousness has been established (see paragraph bridging pages 3 and 4 of the Office Action).

To establish a *prima facie* case of obviousness, three basic criteria must be met: 1) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) a reasonable expectation of success; and 3) the references must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143.

Additionally, it is impermissible to apply the benefit of hindsight in order to arrive at a verdict of obviousness. See, e.g., *Panduit Corp. v. Dennison Manufacturing Co.*, 227 USPQ 337, 343 (Fed. Cir. 1985), *vacated & remanded*, *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, L. Ed. 2d 817, 106 S. Ct. 1578, 229 USPQ 478 (1986), *on remand*, 810 F2d 1561, 1 USPQ2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S. Ct. 2187, 95 L. Ed. 2d 843 (1987), quoting *W.L. Gore Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983):

It is difficult but necessary that the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.

The Office Action has improperly combined the references because as admitted by the Office Action at the top of page 4, the combined references motivate one to use bikunin to “treat human disease such as ARDS”. However, the claimed methods treat COLD and not ARDS, and as discussed above, ARDS and COLD are *distinct*.

The Office Action, also uses impermissible hindsight by combining the references, because at the time the invention was made, one skilled in the art would not have understood that bikunin would accelerate the rate of mucociliary clearance of a subject with chronic obstructive lung disease. The Office Action at the top of page 4 states that the combined references motivate one to use bikunin to “treat human disease such as ARDS”; and as discussed above, methods of treating ARDS and the claimed methods are *distinct*. In short, the alleged teaching is found, not in the references but in the present application, and it is improper to use reconstruct the claimed

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invention from the prior by using the rejected claim as a blueprint or template. *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 548 (Fed. Cir. 1985).

Therefore, based on the criteria of both the establishment of the *prima facie* case of obviousness and the impermissible use of hindsight, the combined references cannot make obvious the claimed invention as of the time of filing.

Accordingly, withdrawal of the rejection of claims 1-10, 14 and 16-29 under 35 U.S.C. §103(a) is respectfully requested.

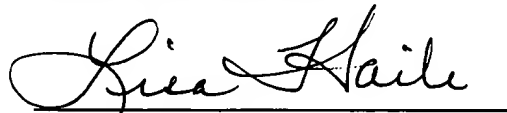
### Conclusion

Applicants submit that the pending claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections, and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged to contact the undersigned below.

No fee is believed due in connection with this Amendment. Check No. 579389 in the amount of \$790.00 is attached as fee for the Request for Continued Examination. If any additional fees are due, the Commissioner is hereby authorized to charge any fees that may be required by this paper to Deposit Account No. 07-1896. A duplicate copy of the Transmittal Sheet is attached.

Respectfully submitted,

Date: October 3, 2005



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**ARDS: Acute Respiratory Distress Syndrome.** A fulminant lung condition in which trauma to the lungs leads to inflammation of the lungs, accumulation of fluid in the alveolar air sacs, low blood oxygen, and respiratory distress.

In ARDS there is sudden respiratory failure due to the rapid accumulation of fluid in the lungs following an abrupt increase in the permeability of the normal barrier between the capillaries and the air sacs in the lungs. In ARDS, the tiny blood vessels (capillaries) in the lungs or the air sacs (alveoli) are damaged. Fluid leaks from the blood vessels into air sacs of the lungs. While some air sacs fill with fluid, others collapse. When the air sacs collapse or fill up with fluid, the lungs can no longer fill properly with air and the lungs become stiff. And without air entering the lungs properly, the amount of oxygen in the blood drops. ARDS is the most serious response to acute lung injury.

ARDS is not a specific disease. It is a response to acute injury of the lungs. The types of trauma that may lead to ARDS are very diverse and include breathing in vomited stomach contents (aspiration), inhalation of smoke or fumes toxic to the lungs, widespread infection of the lungs as in bilateral pneumonia, sepsis (bloodstream infection), near-drowning, a major blood loss, shock, direct trauma to the chest, and some drug overdoses.

ARDS forces the muscles of the lungs to work harder causing labored breathing (huffing and puffing). Despite the effort, breathing is inefficient. There is hypoxemia (an abnormally low level of oxygen in the blood), a characteristic feature of ARDS.

ARDS is a life-threatening condition. Treatment frequently involves the use of oxygen and a mechanical ventilator to help breathing. Breathing failure can occur very quickly after the condition begins. It may take only a day or two for fluid to build up. The process that causes ARDS may continue for weeks. If scarring occurs, this will make it harder for the lungs to take in oxygen and get rid of carbon dioxide.



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ARDS is also known as adult respiratory distress syndrome, stiff lung, shock lung, and wet lung.

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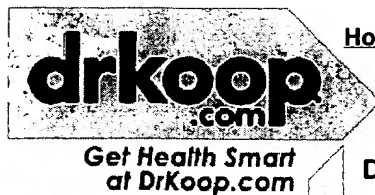


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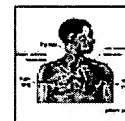
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## ARDS (acute respiratory distress syndrome)

## Definition:

Acute respiratory distress syndrome (ARDS) is a life-threatening condition in which inflammation of the lungs and accumulation of fluid in the air sacs (alveoli) leads to low blood oxygen levels. While it shares some similarities with [infant respiratory distress syndrome](#), its causes and treatments are different.

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#### Alternative Names:

Non-cardiogenic pulmonary edema; Increased-permeability pulmonary edema; Stiff lung; Shock lung; Adult respiratory distress syndrome; Acute respiratory distress syndrome

#### Causes, incidence, and risk factors:

ARDS is a medical emergency. It can be caused by any major lung inflammation or injury. Some common causes include pneumonia, septic shock, trauma, aspiration of vomit, or chemical inhalation. ARDS develops as inflammation and injury to the lung and causes a buildup of fluid in the air sacs. This fluid inhibits the passage of oxygen from the air into the bloodstream.

The fluid buildup also makes the lungs heavy and stiff, and the lungs' ability to expand is severely decreased. Blood concentration of oxygen can remain dangerously low in spite of supplemental oxygen delivered by a mechanical ventilator (breathing machine) through an endotracheal tube (breathing tube).

Typically patients require care in an intensive care unit (ICU). Symptoms usually develop within 24 to 48 hours of the original injury or illness. ARDS often occurs along with the failure of other organ systems, such as the liver or the kidneys. Cigarette smoking may be a risk factor.



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## Definition of Chronic obstructive lung disease (COLD)

**Chronic obstructive lung disease (COLD):** Any disorder that persistently obstructs bronchial airflow. COLD mainly involves two related diseases – chronic bronchitis and emphysema. Both cause chronic obstruction of air flowing through the airways and in the lungs. The obstruction is generally permanent and progresses (becomes worse) over time.

In asthma there is also obstruction of airflow out of the lungs, but the obstruction is usually reversible and between attacks of asthma the flow of air through the airways is usual.

COLD is also called chronic obstructive pulmonary disease (COPD).

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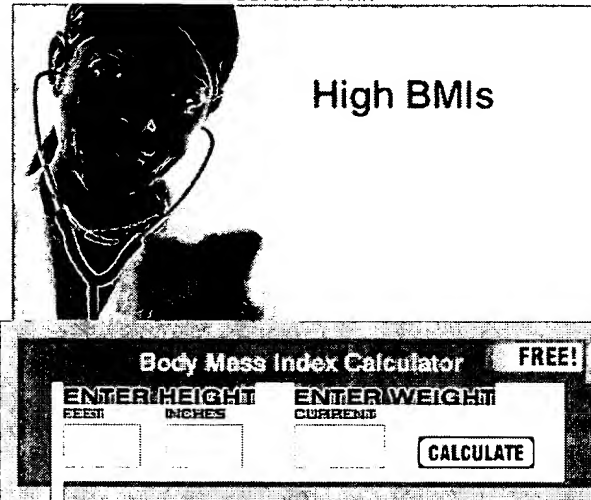
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## Definition of Chronic bronchitis

**Chronic bronchitis:** Defined clinically as a daily cough with production of sputum for months, two years in a row.

In chronic bronchitis, there is inflammation and swelling of the lining of the airways with narrowing and obstruction of the airways. The inflammation stimulates production of (sputum), which can cause further obstruction of the airways.

Obstruction of the airways, especially with mucus, increases the likelihood of bacterial infections.

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#### Suggested Reading By Our Doctors:

- [Chronic Obstructive Pulmonary Disease](#)  
- Chronic Obstructive Pulmonary Disease is comprised primarily of two related diseases - chronic bronchitis and emphysema. Source: MedicineNet



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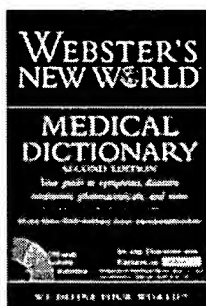
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- [Asthma Complexities](#) - Asthma can often have unusual symptoms. Symptoms of asthma may also vary from individual to individual in type and duration.

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## Cystic Fibrosis Information:

Most of us have heard of cystic fibrosis (CF), and know that it is a life sapping disease that primarily affects children, more to it than that.

### What is CF?

Cystic fibrosis is a relatively rare, inherited disease that affects the lungs and digestive system. The disease is chronic, progressive and ultimately fatal. It is estimated that there are about 30,000 people in the United States who are affected and between 2,500 and 3,000 babies who are born with it each year. CF can occur in all races, but it is most common among Caucasians who have a Northern European heredity.

#### **Learn About Genetic Risk**

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[www.cedars-sinai.edu](http://www.cedars-sinai.edu)

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### What Causes it?

CF is hereditary. Children contract it as the result of both parents passing on an abnormal gene. The parents/carriers affected themselves by the abnormal gene and, until a few years ago, had no way of even knowing that they were carriers. Fortunately, since the 1990's tests have been available so parents can determine if they are carriers of the abnormal gene.

### What it is not

CF is NOT contagious and you cannot catch CF from a person who has it.

### What Does the Disease do?

CF causes the exocrine glands (which produce sweat and mucus), to produce abnormal secretions - unusually thick, that clogs the lungs and leads to chronic respiratory problems. The mucus also obstructs the ducts in the pancreas preventing digestive enzymes from reaching the intestines and helping to properly digest food. As a result, people with CF have trouble breathing and absorbing nutrients and as well as eliminating non-digested food.

### What are the Symptoms of CF?

- Diarrhea that does not go away
- Foul-smelling stools
- Frequent episodes of wheezing
- Persistent cough
- Salty-tasting skin
- Poor growth
- Chronic sinus infection

### Treatment of CF

Treatments for CF are designed to minimize the severity of the symptoms as well as slow the advancement of the disease. The earlier the disease is diagnosed and treatment begins, the more effective the treatments will be.

### How is CF treated?

Treatment follows two paths.

Addressing the problems related to obstruction of the lungs utilizing:

**Physical Therapy** - daily percussion and postural drainage (clapping on the back), helps to loosen lung secretions and coughing. Exercise which helps loosen mucus, stimulate coughing, improve overall physical condition and medication reduce mucus and antibiotics to treat lung infections

**Managing the digestive problems through:**

- eating an appropriate diet (well balanced, high calorie, low fat, high protein)
- taking pancreatic enzymes to aid food absorption and digestion
- taking vitamin supplements
- ongoing treatments for intestinal obstructions

Prevention and cure of CF is not currently possible. With medical intervention the disease can be managed effectively sufferers are living longer due to advances in medical knowledge. (The median age for survival for a person born with their mid 30's and growing, with some living beyond age 40). Researchers are continuing to develop more effective treatments and hope to someday be able to eradicate the disease entirely.

By Murray

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Lucille Packard Children's Hospital

The Lucille Packard Children's Hospital at Stanford provides a great deal of information on children's health care as well as an extensive on line library of information regarding diseases that affect children.

University of Maryland Medical Center

The University of Maryland Medical Center provides comprehensive list of lung diseases as well as understandable (for non medical people) explanation of those diseases, symptoms and treatments.

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